UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANIEL BOURBIA, individually and on behalf of all others similarly situated, Plaintiff, vs. S.C. JOHNSON & SON, INC., Defendant.	Civil Action No. 18-cv-03944 Hon. Paul A. Crotty

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S PUTATIVE CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

PRELIMINARY STATEMENT

Plaintiff Daniel Bourbia's putative class action is predicated upon allegations that because Defendant S. C. Johnson & Son, Inc.'s ("SC Johnson" or "Defendant") Off! FamilyCare Clean Feel Insect Repellent II product (the "Product") did not work to his satisfaction, the core product claims on the label are false. Specifically, Plaintiff disputes the basic claims on the Product label that the Product "repels mosquitoes," provides "effective protection from mosquitoes," or is even an "insect repellent." (Compl. ¶¶ 2, 9.) Each of these claims, indeed every single efficacy claim on the label of the Product, was scrutinized and approved by the Environmental Protection Agency ("EPA" or the "Agency") based on efficacy data demonstrating repellency. The submission and scrutiny of such data were mandated by federal law, regulations, and notices governing the registration of public health pesticides, such as skin-applied insect repellents. These same federal laws and regulations require SC Johnson to use only the EPA-approved label claims, the very claims here that Plaintiff asserts are misleading and deceptive under state law.

Plaintiff's unsupported attack on the approved label claims is not only without merit; the claims fail on their face as the applicable law expressly forbids Plaintiff's state law claims. Pursuant to the governing pesticide regulation, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136, *et seq.*, "[a] State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from" those required by FIFRA. As the Supreme Court has repeatedly held in recent years, efforts like Plaintiff's to impose liability under state law for a federally-approved label constitute additional and different "requirements for labeling" for purposes of preemption. Indeed, such state law claims no less

impose preemptible requirements for labeling than would a state statute explicitly seeking to override federal labeling laws.

In his pre-motion submission to the Court, Plaintiff indicated that he would seek to defend his Complaint based upon the Supreme Court's decision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). Plaintiff, however, has thoroughly misread the applicability of the *Bates* opinion. The *Bates* Court permitted certain state law claims to survive a preemption defense, where such claims were *unrelated to labeling* and instead were related to the performance of an agricultural pesticide for which the EPA in 1979 had waived the submission and review of efficacy data. These circumstances are wholly inapplicable here. First, Plaintiff's entire theory of the case is that the EPA-approved label is false or misleading, and this action thus solely arises from, and is related to, labeling. Second, unlike the agricultural pesticides in *Bates*, the Product's efficacy data is specifically reviewed by the EPA. In fact, at all times the EPA notices and regulations under FIFRA have required the submission of efficacy data for insect repellents such as the Product, and the EPA will approve a label for an insect repellent only if it judges the efficacy data sufficient to support the label claims of efficacy. Without the background of the waiver of efficacy review or claims unrelated to labeling, Plaintiff's reliance on *Bates* is misplaced. Instead, Plaintiff's state law claims pose a direct challenge to the EPA and the federal regulatory regime applicable to the Product, and should accordingly be dismissed in their entirety.[1]

[1] As discussed briefly below, such claims are also deficient on their own terms, but the Court need not address such deficiencies in light of preemption.

STATEMENT OF FACTS

A. The Product

The Product at issue, Off! FamilyCare Clean Feel Insect Repellent II, bears an EPA-approved label stating that it "repels mosquitoes[]"[2] and provides "effective protection against mosquitoes." (Compl. ¶ 2; a copy of the current EPA-approved label is attached to the accompanying declaration of James D. Arden ("Arden Decl.") as Exhibit A.) As disclosed on the label, the Product is EPA-registered, bearing EPA Reg. No. 4822-536, and its active ingredient is picaridin (in a 5% formulation). (Ex. A.)

B. EPA Regulation of Public Health Pesticides and Insect Repellents

Public health pesticides and insect repellents are intended to help protect people from pests that may spread disease and thus pose a risk to public health, such as mosquitoes and ticks. Due to the significance of these products, federal law requires that a person seeking to market a pesticide must first register it with the EPA pursuant to procedures governed by FIFRA and the implementing regulations enacted thereunder (*see* 40 CFR §§ 152-59). Under the regulations governing insect repellents, the EPA is obligated to review performance data before deciding whether it will register the product. 44 Fed. Reg. 27932, 27939 (1979); *see also* EPA's Label Review Manual (hereafter "Manual") at 4-8, available at https://www.epa.gov/sites/production/files/2018-04/documents/lrm-complete-mar-2018.pdf (efficacy review required for insect repellents, *i.e.*, "Invertebrate Control" products).[3]

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[2] The claim on the label states "repels mosquitoes that may carry [the] Zika Virus[,] Dengue Virus[, and] West Nile Virus." *See* excerpts of label at Compl. ¶ 2 and full label at Arden Decl. Ex. A.

[3] "Invertebrate Control" products are products "intended for use in or on humans (or in or on pets for control of pests which attack human such as fleas, ticks, mosquitoes, and biting flies) . . . to control pests of sanitary or public health significance such as those above . . . ." Manual at 4-8. The EPA web page linking to the Manual (https://www.epa.gov/pesticide-registration/label-review-manual) states that the

An applicant for registration must file a statement including "a complete copy of the labeling of the pesticide, a statement of all claims for it, and any directions for use," together with "a full description of the tests made and results thereof upon which the claims are based." 7 U.S.C. §§ 136a(c)(1)(C), (F). Prior to registration and after "draft label texts have been provisionally accepted by the Agency," the product's final printed labeling must be submitted and approved. 40 CFR § 156.10(6)(i).[4]

Absent special circumstances not relevant here,[5] the Agency will register the pesticide if it determines, *inter alia*, that the pesticide is efficacious (*i.e.*, "its composition is such as to warrant the proposed claims for it"), § 136a(c)(5)(A); *see* 40 CFR 152.112(d) (EPA will approve an application under the criteria of FIFRA § 136a(c)(5) only if "[t]he Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it") and that its label complies with the requirements of FIFRA § 136a(c)(5)(B) and is not misbranded, 40 CFR § 152.112(f). Such determination follows a careful review of "all relevant data in the possession of the Agency" and a determination "that no additional data are necessary to make the determinations required by FIFRA § 3(c)(5)." 40 CFR § 152.112(b), (c).

Manual "compiles existing interpretations of statutory and regulatory provisions and reiterates existing Agency policies."

[4] The EPA approves a "master label" containing all of the approved uses for a given pesticide product that is the exclusive source of claims on the product label in the market. *See* Manual at 3-2 ("Labeling for a given product must not contain any text beyond that which is approved in the master label[.]").

[5] The EPA has waived efficacy review for products not at issue here—most notably agricultural pesticides—pursuant to 7 U.S.C. § 136a(c)(5) ("In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy.").

In assessing the data submitted by the applicant in support of the product label claims, the EPA determines "whether the data submitted or cited to fulfill the data requirements specified in this part are acceptable . . . based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement." 40 CFR § 158.70(a). The EPA has published guidelines on standards for conducting "acceptable tests" and reporting and evaluating data, including suggested study protocols, in accordance with 40 CFR § 158.70(c).

Upon registration, the pesticide may be sold only with the approved label claims—it is unlawful to use any substantially different claims from those approved in connection with its registration. 7 U.S.C. §§ 136j(a)(1)(B), (E) (making it unlawful to distribute or sell "any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration" or "any pesticide which is . . . misbranded"). A registrant seeking to change the composition of a pesticide formulation or certain language on its approved label must apply for a registration amendment, which the EPA will approve only if it determines that the change "will not violate any provision of this subchapter." *Id.* § 136a(f)(1). The amendment request must be supported by a data submission in either of two circumstances: when the proposed amendment to the label involves "a new use, a new application rate, or a change in precautionary statements" or "when there is a new public health claim (such as control of a human pathogen or control of mosquitoes)." Manual at 4-7.

The EPA's Label Review Manual emphasizes the importance of the contents of the approved label, including the directions for use: "Unlike other types of product labels, pesticide labels are enforceable and must include the statement, 'It is a violation of Federal law to use this

product in a manner inconsistent with its labeling.' 40 CFR § 156.10(i)(2)(ii). In other words, ***the label is the law***." Manual at 1-2 (emphasis in original).

C. EPA Review and Approval of the Product's Efficacy Data and Label Claims

In 2001, the EPA approved the registration and label of the Product, then bearing the name "KBR 3023."[6] The approved label claims included the following statements:

- Effective protection from mosquitoes, biting flies and fleas.
- Repels insects for up to 3 to 4 hours.

Arden Decl. Ex. B, available at https://www3.epa.gov/pesticides/chem_search/ppls/003125-00547-20011201.pdf.

In a preregistration EPA "Efficacy Study Review" dated April 17, 2000, the EPA entomologist who reviewed the efficacy data provided by field studies of the Product found the data to be acceptable and to support a mosquito repellency claim of 3-4 hours for the label.[7] In addition, laboratory studies were submitted as supportive and classified as "supplementary" to the field studies, because the laboratory studies did not include untreated control data. *Id*.

A subsequent review of efficacy data was summarized in an EPA "Product Performance Review" dated January 25, 2006, in connection with an amendment request to add a claim of repellency to mosquitoes that may carry the West Nile Virus to the Product's label.[8] The same

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[6] *See* EPA New Pesticide Fact Sheet, at 1, available at https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-070705_01-May-05.pdf.

[7] A copy of the Efficacy Study Review is submitted as Arden Decl. Ex. C and also is available at https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/070705/070705-2000-04-17a.pdf.

[8] A copy of the Product Performance Review is submitted as Arden Decl. Ex. D and also is available at https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/070705/070705-2006-01-25a.pdf. The document shows the Product Name as "KBR 3023" with EPA Reg. No. 4822-536. It has attached to it a copy of a published study of KBR 3023, Yap, *et al.*, "Field efficacy of four insect repellent

EPA entomologist who had reviewed efficacy data in 2000 concluded: "The existing data and published studies support a WNV [West Nile Virus] claim." *Id.* at 1. He also observed that "there were data submitted with the original registration that supported West Nile virus claims as well." *Id.*

On February 18, 2016, the EPA approved an amendment to the Product label to add claims of repellency against mosquitoes that may carry the Dengue virus and the Zika virus. Arden Decl. Ex. E.[9] Among the approved label claims were the two core claims approved in 2001: "Effective protection from mosquitoes . . ." and "Repels insects for up to 3-4 hours." *Id.* at 3.[10]

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products against vector mosquitoes in a tropical environment," *Journal of the American Mosquito Control Association* 13(3): 241-44 (2000).

[9] A copy of the approved label and transmittal letter from EPA, which is submitted as Arden Decl. Ex. E, is available at https://www3.epa.gov/pesticides/chem_search/ppls/004822-00536-20160218.pdf.

[10] Judicial notice of the EPA website and the documents maintained on that site may be taken on a motion to dismiss because the sources of such materials cannot reasonably be questioned under Fed. R. Evid. 201(b)(2). *See, e.g.*, *Goldman v. Barrett*, No. 15 Civ. 9223, 2017 WL 4334011, at *1 n.3 (S.D.N.Y. Jul. 25, 2017) (taking judicial notice of records on Pennsylvania Secretary of State's website), citing numerous cases including: *Lefebvre v. Morgan*, No. 14 Civ. 5322, 2016 WL 1274584, at *13 n.17 (S.D.N.Y. Mar. 31, 2016) (taking judicial notice of the New York State Department of Civil Service website on a motion to dismiss); *Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 166 (S.D.N.Y. 2015) (noting "it is clearly proper to take judicial notice" of "documents retrieved from official government websites"); and *Munaron v. Munaron*, 862 N.Y.S.2d 796 (Sup. Ct. 2008) (finding judicial notice can be taken, as a matter of public record, of an entry on an official Secretary of State website). Applications to federal agencies for label approval have been judicially noticed on motions to dismiss even where the documents are not posted on the agencies' websites, because the authenticity of the documents could not be reasonably disputed. *See La Vigne v. Costco Wholesale Corp.*, 284 F. Supp. 3d 496, 504-05 (S.D.N.Y. 2018) (taking judicial notice of food label applications to Department of Agriculture on motion to dismiss); *Nelson v. MillerCoors LLC*, 246 F. Supp. 3d 666, 673 (E.D.N.Y. 2017) (taking judicial notice of applications for label approval on motion to dismiss).

ARGUMENT

I. Plaintiff's Claims are Expressly Preempted by FIFRA and the Regulations Promulgated Thereunder by the EPA.

All of Plaintiff's claims, which challenge statements on the label of the Product, are expressly preempted by FIFRA and the regulations and notices promulgated thereunder by the EPA. These rules, as described *supra*, expressly require manufacturers to obtain approval of a public health pesticide, such as a mosquito repellent, and its label based on the product's effectiveness. *See* 7 U.S.C. § 136 *et seq.* FIFRA expressly preempts state-imposed requirements for labeling or packaging that are in addition to or different from those required by the EPA. *See id.* at § 136v(b).[11]

A. The EPA Reviewed Efficacy Data Submitted by the Applicant Before Registering the Product and Approving its Labeled Efficacy Claims.

An applicant is obligated to submit and the EPA is obligated to review efficacy data (also referred to as product performance data) before it will register any public health pesticide, including "invertebrate control products intended for use in or on humans . . . to control pests such as . . . mosquitos." 44 Fed. Reg. 27932, 27938-27939 (1979); Manual at 4-8 – 4-9.[12] Efficacy studies "document how well pesticide products perform as pest control agents," and may include "tests to determine the lethality of a formulation against a certain pest species, to

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[11] The preemption provision of FIFRA provides, *inter alia*, that a state shall not impose "any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b).

[12] Available at https://www.epa.gov/sites/production/files/2018-04/documents/lrm-complete-mar-2018.pdf. *See also* 40 CFR § 158.70 ("The Agency will determine whether the data submitted or cited to fulfill the data requirements specified in this part are acceptable . . . based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement.").

document effectiveness under actual use situations, and/or to determine whether claims beyond mere control are supported (i.e., length of a residual effect)." Manual at 4-8.[13]

To satisfy the requirement that it submit to the EPA product performance data to support its labeled claims, the applicant submitted laboratory and field efficacy studies on the Product. The EPA reviewed these studies during and after the registration of the Product under EPA Reg. No. 3125-547 (which later became EPA Reg. No. 4822-536) and determined that the efficacy studies supported the mosquito repellent claims on the Product's label, including the approved claim "Effective protection from mosquitoes . . . Repels insects up to 3 to 4 hours." *See* Arden Decl. Exs. B - E.

B. A Determination in Favor of Plaintiff Would Amount to a State Rule or Requirement at Odds with the EPA-Approved Product Label.

Under FIFRA's preemption provision, a state may not impose "any requirements for labeling or packaging in addition to or different from those required" under FIFRA itself or the regulations promulgated thereunder. 7 U.S.C. § 136v(b). Once a product is registered and its label approved, a pesticide registrant generally may not modify the label approved by the EPA without EPA approval. 7 U.S.C. § 136j(a)(2)(A); *see also Hawkins v. Leslie's Pool Mart, Inc.*, 184 F.3d 244, 251 (3d Cir. 1999) ("FIFRA disallows any changes to an EPA-approved label unless the EPA approves the change.").

Here, the EPA reviewed SC Johnson's product performance data before and after the registration process and expressly determined that the submitted efficacy studies supported the

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[13] According to the EPA Product Performance Test Guidelines, OPPTS 810.3700, "Insect Repellents to be Applied to Human Skin," which governs submissions for any new insect repellant data, "[t]he objective of most repellant efficacy testing to support registration is to estimate how long after treatment a repellant will continue to protect users from the target pest[.]" *Id.* at p. 7, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0150-0011.

mosquito repellent claims on the Product's label, including the approved claim "Effective protection from mosquitoes . . . Repels insects up to 3 to 4 hours." *See* EPA Regs. 3125-547; 4822-536. As such, Plaintiff's challenge to the Product label amounts to a "requirement[] for labeling or packaging . . . different from" the label approved by the EPA—any "determination in favor of [P]laintiff on those causes of action would amount to a state rule or requirement at odds with the EPA-approved" label. *See Esposito v. Contec, Inc.*, 147 A.D.3d 1384, 1386 (4th Dep't 2017). The Fourth Department in *Esposito* affirmed the dismissal of failure to warn and strict liability claims because the claims addressed matters covered by the EPA-approved label. It reasoned:

> The first and second causes of action allege that defendant promoted or encouraged an unsafe use of its product and thus failed to instruct users against such unsafe use. We conclude that any jury verdict or court determination in favor of plaintiff on those causes of action would amount to a state rule or requirement at odds with the EPA-approved warning label on the product, i.e., a state rule relating to labeling and packaging that would impose requirements additional to or different from those imposed by the federal statute and regulations. We reach the same conclusion with regard to the fourth cause of action insofar as it alleges defendant's strict liability to plaintiff for "failing to provide adequate warnings" and for "failing to provide adequate instruction and direction of a safe use of the product."

Id. at 1386-87. Only claims "unrelated to labeling" were allowed to proceed. *Id.*; *see also Jarman v. United Industries Corp.*, 98 F. Supp. 2d 757, 760-62 (S.D. Miss. 2000) (state law claims against termiticide manufacturer alleging that product's package labeling overstated its efficacy were preempted by FIFRA, absent evidence federal government registered product without evaluating manufacturer's efficacy claims). Indeed, "[t]o allow a jury to pass judgment on Defendant's labels, notwithstanding the [agency]'s approval, would disrupt the federal

regulatory scheme." *Meaunrit v. The Pinnacle Foods Grp. LLC*, No. C 09-04555, 2010 WL 1838715, at *7 (N.D. Cal. May 5, 2010).[14]

In this case, all of Plaintiff's causes of action relate to the core EPA-approved label claims of "effective protection against mosquitoes" and "repels insects for up to 3-4 hours." All claims are therefore preempted.

C. Preemption Has Narrower Scope Where the EPA has Waived its Review of Product Performance Data for Labeled Efficacy Claims.

In its May 11, 1979 Federal Register Notice (the "Notice"), the EPA informed the public, *inter alia*, that it would exercise the authority Congress granted it in 1978 to waive efficacy data requirements for agricultural pesticides as well as the statutory requirement that the Agency confirm the efficacy claims made on agricultural pesticide labels. 44 Fed. Reg. 27932, 27938-27939 (1979);[15] Manual at 4-8 ("[T]he Agency routinely waives the submission . . . of efficacy data for most products (*except for the types of products listed below*)") (emphasis added). This Notice, however, made clear that the Agency was *not* waiving the requirement that an applicant submit efficacy data to support efficacy claims made for public health uses on the label of a pesticide, including personal insect repellents. *Id.*; *see also* 7 U.S.C. §§ 136(nn) – (oo) (defining

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[14] *See also La Vigne v. Costco Wholesale Corp.*, 284 F. Supp. 3d at 507-11 (dismissing cause of action under GBL § 349 and similar state consumer protection statutes as preempted by the federal Poultry Products Inspection Act ("PPIA")—which contains a preemption provision analogous to FIFRA's—because claims alleging labeling deficiencies regarding defendant's product imposed requirements different from or additional to federal requirements under PPIA and its corresponding regulations, and because the U.S. Department of Agriculture's Food Safety Inspection Service had previously reviewed and approved the label).

[15] As shown by the legislative history, Congress believed that product performance issues for agricultural pesticides were adequately addressed by information from government and university sources and market forces. *See* S. Rpt. 95-334, 95th Cong., 1st Sess. 20 (Jul. 6, 1977). The EPA believed that waiving review of the efficacy of agricultural pesticides in the registration process would enable the Agency to focus on its "primary mandate under FIFRA": investigating "the health and safety aspects of pesticides." 47 Fed. Reg. 53192 (Nov. 24, 1982); 47 Fed. Reg. 40659, 40661 (col.1) (Sept. 15, 1982).

"public health pesticide" under FIFRA to include minor use pesticide products registered for mosquito control use).

Although some courts have attempted to limit the scope of express preemption under FIFRA, these cases specifically involved agricultural pesticides for which the EPA has waived review of product efficacy data. *See* 7 U.S.C. § 136a(c)(5) ("In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy.").

For example, in *American Cyanamid Co. v. Geye*, 79 S.W.3d 21 (Tex. 2002), the Texas Supreme Court held that state law claims against a herbicide manufacturer for crop damage allegedly caused by mixing herbicides according to label instructions were not preempted by FIFRA because the EPA had chosen not to regulate herbicide product labeling with respect to efficacy:

> [H]ere we must determine the breadth, not of the preemption itself, but of an exception to that preemption founded on Congressional authorization for the EPA to specifically choose to not collect efficacy data. Acting on that authorization, the EPA has chosen not to evaluate whether a product will be toxic to the crops it was intended to assist. Because the EPA does not evaluate whether a product will be toxic to the crops that it was intended to assist, the EPA does not regulate a product's labeling claims on this subject. *Because the scope of FIFRA's preemption is dependent on what the EPA regulates*, FIFRA does not preempt the [plaintiff]'s common law crop-damage claim.

Id. at 29 (emphasis added).

Three years later, in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), the Supreme Court followed the same reasoning as the Texas Supreme Court in *American Cyanamid*. The Supreme Court recited in detail the FIFRA amendments authorizing the waiver of efficacy data

and the EPA's decision to use that authority to waive efficacy review of agricultural pesticides.[16] It was explicitly against the background of that waiver that the Court concluded that some state law claims were not preempted. For example, a cause of action for breach of express warranty against a herbicide manufacturer was not preempted by FIFRA because such a claim "asks only that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product" and, as the Court noted, "[r]ules that require manufacturers to . . . honor their express warranties . . . plainly do not qualify as requirements for 'labeling or packaging.'" *Id.* at 444. The herbicide label at issue stated:

> Dow AgroSciences warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below.

Id. at 444 n.16. Unlike the label in *Bates*, for which the EPA had waived review of efficacy data and the manufacturer had expressly undertaken to "warrant[]" its product's performance, SC Johnson's Product label contains only those efficacy claims approved by the EPA after an Agency entomologist reviewed field and laboratory studies on file.[17] In approving the Product's label, the EPA determined that the submitted efficacy studies supported the mosquito repellent

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[16] In addition to the FIFRA amendments and regulations thereunder, the Supreme Court referred specifically to Pesticide Regulatory Notice 96-4, issued by EPA in 1996 in response to certain court decisions based on the false assumption that the EPA had assessed the efficacy data and claims of agricultural pesticides, such as the product at issue in *Bates*. The Court noted that PRN 96-4 "clarified" that EPA approval of the label of an agricultural pesticide "does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." 544 U.S. at 440.

[17] The EPA entomologist's reviews of efficacy data in 2000 and 2006 both cite the Agency's test guidelines for "Treatments to Control Pests of Humans and Pets," OPPTS 810.3300, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0150-0006. EPA published OPPTS 810.3300 in 1998. The Agency's product performance regulations, 40 CFR 158.202(i) (2000 edition), and its OPPTS 810.3300 test guidelines implemented the EPA's decision (cited in *Bates*) to waive efficacy data for agricultural pesticides but to continue the requirement to submit efficacy data for public health pesticides, including invertebrate control products intended for use on humans to control pests such as mosquitoes. 44 Fed. Reg. 27932, 27939.

claims on the Product's label, including the approved claim "Effective protection from mosquitoes . . . Repels insects up to 3 to 4 hours." *See* EPA Regs. 3125-547; 4822-536.

Both *American Cyanamid* and *Bates* were decided within the specific confines of the EPA's waiver of product performance data review for agricultural pesticides. Notably, both courts acknowledged that the EPA did not waive such review in other cases. In *American Cyanamid*, the court noted that the EPA "has chosen not to collect efficacy data for any products except in a specific set of circumstances that are not relevant here." 79 S.W.3d at 25. In *Bates*, the Supreme Court expressly noted that efficacy review for the agricultural pesticide at issue was waived and that the waiver included "limited qualifications not applicable here." 544 U.S. at 440. These "specific set of circumstances" and "limited qualifications" maintained the requirement of efficacy review for personal insect repellents.[18] Thus, unlike the situation before the courts in *American Cyanamid* or *Bates*—in which no efficacy data on the agricultural product at issue had been submitted to or reviewed by the EPA in connection with the product's labeled efficacy claims—here, the EPA reviewed efficacy data on Defendant's Product and expressly approved the mosquito repellent's labeled efficacy claims.

Moreover, even under *Bates,* state law claims that challenge an approved label are preempted. As the Supreme Court subsequently recognized in *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), *Bates* merely held that claims that do not involve a "requirement '*for labeling or packaging*' . . . [fall] outside the class of claims covered by the express pre-emption provision at issue in that case." *Id.* at 491 (emphasis in original). The Court in *Mutual*

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[18] *See* 44 Fed. Reg. 27932 (1979); Manual at 4-8 – 4-9 (listing "invertebrate control" products "intended for use in or on humans . . . for control of pests which attack humans such as . . . mosquitoes" as a type of product "requiring submission of efficacy data").

Pharmaceutical also noted that, under *Bates*, the state law "requirements" prohibited by the express preemption provision are broad enough even to "embrace common law duties" under which federally-approved label claims are alleged to be false or misleading. *Id.* at 492. Accordingly, all of Plaintiff's claims, which assert state statutory or common law duties that the EPA-approved label claims allegedly violate, are preempted for imposing requirements different from the federal requirements.

II. Plaintiff's Claims are Preempted under the Doctrine of Conflict Preemption.

Plaintiff's claims challenging the Product label also fail under the doctrine of conflict preemption, where it is "impossible for a private party to comply with both state and federal requirements." *Mutual Pharmaceutical*, 570 U.S. at 480. "[M]anufacturers have a continuing obligation to adhere to FIFRA's labeling requirements" and must obtain EPA approval before amending the label on a product subject to the regulations promulgated under FIFRA. *Bates*, 544 U.S. at 438-39 (citing 7 U.S.C. §§ 136j(a)(1)(E) and 136a(f)(1)); *see also Hawkins*, 184 F.3d at 251 ("FIFRA disallows any changes to an EPA-approved label unless the EPA approves the change."). While Plaintiff alleges that no conflict exists because neither FIFRA nor the EPA *commands* that Defendant sell its Product at all,[19] the Supreme Court rejected this very argument in *Mutual Pharmaceutical*:

> We reject this "stop-selling" rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to

[19] In its letter to the Court dated Jul. 3, 2018 (Doc. 13, at 2), Plaintiff's counsel asserted "[n]either FIFRA nor the EPA commands that Defendant sell its defective, worthless product" and that such allegation meant "there is no conflict here" under the language of a concurrence by Justice Thomas in *Wyeth v. Levine*, 555 U.S. 555 (2009). Four years later, Justice Thomas joined the Court's opinion in *Mutual Pharmaceutical* repudiating the "stop-selling" rationale and holding it "incompatible" with the law of preemption. 570 U.S. at 487.

> avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be "all but meaningless."

Id. at 487 (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011)).[20]

The contours of conflict preemption were sharply defined by the Supreme Court in three decisions applying FDA regulations on labeling: *Mutual Pharmaceutical*, *PLIVA*, and *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Wyeth*, the Supreme Court found that a failure to warn claim was not preempted by federal law under conflict preemption because the federal regulation in that case—called a "changes being effected" or CBE regulation—permitted the brand-name drug company to make unilateral revisions to its label. The right of unilateral action meant that Wyeth could have made the revisions required by state law without violating FDA regulations. The Court held: "Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The CBE regulation permitted Wyeth to unilaterally strengthen its warning . . . ." 555 U.S. at 573.

In contrast, FDA regulations do not permit a generic drug company to unilaterally change its label, and that led to a different result in *Mutual Pharmaceutical* and in *PLIVA, Inc. v. Mensing*, *supra*, where the Supreme Court held that state law claims (such as failure to warn) against generic drug manufacturers were preempted. In that regard, Justice Thomas, writing for the majority, assumed that generic drug manufacturers might seek assistance from the FDA in obtaining a new label upon learning of new risks not adequately addressed in the approved label.

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[20] Plaintiff further alleges that the *Bates* Court rejected conflict preemption *sub silentio*, but only a single district court decision out of Hawaii, *Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270 (D. Haw. 2015), supports this conjecture—Defendant has found no other cases making a similar suggestion, and nothing in the *Bates* decision itself supports this notion. In any event, *Bates* addressed a product label that had not been reviewed for efficacy by the EPA, and it was for this reason that the label's efficacy claims lacked preemptive force against certain state claims.

But the state law claims were preempted whether or not the defendants made any requests to the FDA:

> The federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label. [. . .]
>
> The question for "impossibility" is whether the private party could independently do under federal law what state law requires of it. *See Wyeth*, 555 U. S. at 573 (finding no pre-emption where the defendant could "unilaterally" do what state law required).

546 U.S. at 619-20. As the Court further explained, state law claims were not preempted in *Wyeth* because "the CBE regulation, 21 CFR § 314.70(c)(6)(iii), permitted a brand-name drug manufacturer like Wyeth 'to unilaterally strengthen its warning' without prior FDA approval." *Id.* at 624.

There is no CBE regulation under FIFRA, and the EPA does not permit regulated entities to make unilateral changes to EPA-approved labels. For conflict preemption purposes, the Defendant is in the same position as the generic drug companies in *Mutual Pharmaceutical* and *PLIVA*. Thus, state law claims requiring a different label or imposing liability based on an EPA-approved label are also preempted on conflict preemption grounds.

III. Plaintiff Fails to Sufficiently Allege any Causes of Action Pursuant to State Law or the Magnuson Moss Warranty Act.

A. Plaintiff's GBL 349 and 350 Claims Fail under Safe Harbor Provisions.

Plaintiff's causes of action for deceptive acts and false advertising under New York General Business Law ("GBL") §§ 349 and 350 also fail pursuant to the safe harbor provisions in those statutes, which exclude challenges to federally-regulated matters. Section 349(d) provides: "In any such action it shall be a complete defense that the act or practice is . . . subject to and complies with the rules and regulations of, and the statutes administered by, . . . any

official . . . agency of the United States[.]" Section 350 is subject to a similar provision: "In any such action it shall be a complete defense that the advertisement is subject to and complies with the rules and regulations of, and the statutes administered by the Federal Trade Commission or any official department, division, commission or agency of the state of New York." *Id.* at § 350-d. Although § 350-d refers only to regulations administered by the Federal Trade Commission, "the New York courts have construed that statute to cover regulations by other federal agencies as well." *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987); *see also Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (holding that challenged representations comporting substantively with FDA-approved statements "are non-actionable due to the FDA's approval" under GBL §§ 349 and 350, as well as under the Lanham Act). Thus, Plaintiff's causes of action under sections 349 and 350 regarding EPA-approved label statements must fail.

B. Plaintiff's Fraud Claim Fails under Rule 9(b).

Plaintiff's common law fraud claim fails to satisfy the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure, which requires a party to state with particularity the circumstances constituting fraud. Although malice, intent, knowledge, and other conditions of a person's mind may be alleged generally under this rule, a plaintiff must still "allege facts that give rise to a strong inference of fraudulent intent." *Marketxt Holdings Corp. v. Engel & Reiman, P.C.*, 693 F. Supp. 2d 387, 393 (S.D.N.Y. 2010) (internal quotation marks omitted). "A plaintiff may accomplish this by (1) alleging facts to show that defendant had both motive and opportunity to commit fraud, or by (2) alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Id.*

Plaintiff alleges that "[t]he false and misleading representations and omissions were made with knowledge of their falsehood" because "Defendant is a top distributor of pest repellant

products in the United States who is undoubtedly aware of the studies finding that its product does not work." Compl. ¶ 49. These allegations, however, fail to state with sufficient particularity any knowledge on the part of SC Johnson as to these alleged studies, which may conflict with the studies that the EPA evaluated and found supportive of the specific claims on the label, much less knowledge that would "give rise to a strong inference of fraudulent intent." *Id.*; *see also Sable v. Southmark/Envicon Capital Corp.*, 819 F. Supp. 324, 338 (S.D.N.Y. 1993) ("Conclusory allegations of a firm's tax expertise do not satisfy the particularity requirements of Rule 9(b) unless other allegations specifically show how or why the expert should have believed the projections to be inaccurate.").

C. Plaintiff's Unjust Enrichment Claim is Duplicative.

Plaintiff's unjust enrichment claim fails because it is "merely duplicative of [Plaintiff's] other causes of action." *Koenig v. Boulder Brands, Inc.,* 995 F. Supp. 2d 274, 291 (S.D.N.Y. 2014). An unjust enrichment claim "cannot survive where it simply duplicates, or replaces, a conventional contract or tort claim." *Id.* at 290 (internal quotation marks omitted). In *Koenig*, plaintiffs brought a claim for unjust enrichment under New York law, alleging that they had purchased defendants' product because of defendants' purported misrepresentations and that defendants allegedly retained the revenue generated from plaintiffs' purchases. *Id.* at 290-91. Accepting the truth of the allegations in the complaint, the court found that defendants reaped a financial reward at plaintiffs' expense. *Id.* at 291. Nevertheless, the court dismissed plaintiffs' unjust enrichment claim as merely duplicative of their other causes of action, holding that "to the extent that [p]laintiffs' other claims succeed, 'the unjust enrichment claim is duplicative,' and 'if plaintiffs' other claims are defective, an unjust enrichment claim cannot remedy the defects.'" *Id.* (quoting *Corsello v. Verizon New York, Inc.*, 18 N.Y.3d 777, 790-91 (2012) ("[U]njust enrichment is not a catchall cause of action to be used when others fail. It is available only in

unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff.")). *See also Nelson v. MillerCoors LLC*, 246 F. Supp. 3d 666, 679 (E.D.N.Y. 2017) (dismissing duplicative unjust enrichment claim that was "pleaded in the alternative").

D. Plaintiff's Express Warranty Claim Fails Because the Product Label Does Not Constitute a Warranty.

Plaintiff's express warranty claim fails because the Product label statements that Plaintiff alleges constitute warranties—"insect repellent," "repels mosquitoes," and "effective protection from mosquitoes"—are EPA-approved product descriptions, not affirmations of fact or promise by Defendant. *See, e.g.*, *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995). In *Welchert*, the Eighth Circuit reviewed a claim for breach of express warranty based on information that the EPA required a herbicide manufacturer to include on its product label but that plaintiffs claimed was misleading or inaccurate. In holding that FIFRA preempted the state law cause of action for breach of express warranty, the court found that because the manufacturer was required to include the information on the product label, the label statement constituted a "mandated disclosure, not a voluntarily undertaken promise." *Id.* at 72 (internal quotation marks and citation omitted). While the *Welchert* court explicitly recognized the possibility that manufacturers might include misleading or inaccurate information in mandated disclosures, that possibility did not alter the court's decision to bar these claims as preempted:

> A label statement specifically required by FIFRA and its corresponding federal regulations does not have the contractual quality of an express warranty. As noted above, it is in the nature of a mandatory disclosure. Thus, any misrepresentation, negligent or otherwise, in such disclosure would therefore sound, if at all, in tort, not contract.
>
> Where Congress has so clearly put pesticide labeling regulation in the hands of the EPA, the [plaintiffs]' claim challenging the accuracy of the herbicide label's federally-mandated and approved statement cannot survive. [. . .] To hold otherwise would be to allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully

> complied with the specific labeling requirements of its own regulations. In such case, state court consideration of the label statement would be an "additional" requirement.

Id. at 73 & n.6 (citing *Worm v. American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993) ("Because the language on the label was determined by the EPA to comply with the federal standards, to argue that the warnings on the label are inadequate is to seek to hold the label to a standard different from the federal one.")).

E. The Magnuson Moss Warranty Act is Inapplicable.

Finally, Plaintiff's claims under the Magnuson Moss Warranty Act ("MMWA") fail because MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law," such as the label-as-warranty alleged here. 15 U.S.C. § 2311(d). Moreover, the label is a product description and not a guarantee of specified performance. *See, e.g.*, *Hart v. BHH, LLC*, No. 15-cv-4804, 2016 WL 2642228, at *3-4 (S.D.N.Y. May 5, 2016) (dismissing MMWA claim and finding label representing that a product repels pests in a "fast and effective" fashion did not constitute a MMWA warranty); *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 378 (S.D.N.Y. 2014) (finding representation that mouthwash would "restore enamel" was product description, not a promise of performance over a specified time).

CONCLUSION

For the foregoing reasons, the Plaintiff's Complaint should be dismissed in its entirety.

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